Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	March 5, 2013
Contact Person and Address:	Bradley Heil, Regulatory Affairs Specialist T (901) 399-6339 F (901) 566-7831
Name of Device:	Smith & Nephew, Inc. SURESHOT™ Distal Targeting System V3.0
Common Name:	Computer Assisted Surgery System
Device Classification Name and Reference:	21 CFR 882.4560 Stereotaxic Instrument – Class II
Device Class:	Class II
Panel Code:	Neurology/84
Product Code:	OLO

AUG 0 4 2013

Device Description

Subject of this premarket notification are modifications to the SURESHOT™ Targeting System. The modifications to the SURESHOT™ Targeting System V3.0 include the implementation of the drill depth measurement function, the ability to target for 8.5mm Japanese nails, an updated graphical user interface, updates to the Launcher program, and the addition of new drill sleeves.

The SURESHOT™ Targeting System is a computer controlled electromagnetic tracking system. It assists the surgeon in locating and positioning screws in an intramedullary nail implant during orthopedic trauma surgery. The link between the sterile surgical area (patient) and the instrument system is provided through an electromagnetic tracking system. Electromagnetic spatial measurement systems determine the location of instruments that are embedded with sensor coils. When the sensor-embedded instrument is placed inside controlled, varying magnetic fields, voltages are induced in the sensor coils. These induced voltages are used by the measurement system to calculate a 3D virtual position of the instrument. Because the magnetic fields are of a low field strength and can safely pass through human tissue, location measurement of an object is possible without the line-of-sight constraints of an optical spatial measurement system that requires a camera.

The SURESHOT™ Distal Targeting System software is intended to be used with existing Smith & Nephew platform, instruments and implants. New instrumentation has been developed for the drill depth measurement application aspect of the software. The devices subject of this premarket notification include:

- SURESHOT™ Distal Targeting System Software V3.0
- SURESHOT™ Trauma Launcher Software V1.1.1
- SURESHOT™ Drill Depth Inner Drill Sleeves
- SURESHOT™ Drill Depth Outer Screw Sleeve

No new implants are being cleared via this premarket notification.

Technological Characteristics

Software verification and validation testing was completed in line with FDA's guidance document entitled, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff," dated January 11, 2002. A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject device and the software will perform as intended. Clinical data was not needed to support the safety and effectiveness of the subject device.

Intended Use

The Smith & Nephew SURESHOT™ Targeting System is intended to be an intraoperative image guided localization system. It is a computer assisted orthopedic surgery tool to aid the surgeon with drill positioning for screws during intramedullary nail implantation. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. The Smith & Nephew SURESHOT™ Targeting System is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

Substantial Equivalence Information

The substantial equivalence of the SURESHOT™ Targeting System software is based on its similarities in indications for use, design features, sterilization methods and operational principles to the predicate systems listed in the following table.

Table 1: Substantially Equivalent Predicate Systems to SURESHOT™ Targeting System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew	Smith & Nephew PiGalileo Screw Targeting System V1.1	K092497	09/11/09
Smith & Nephew	Smith & Nephew SURESHOT™ Distal Targeting System v.2.0	K100107	02/23/10
Smith & Nephew	Smith & Nephew SURESHOT™ Distal Targeting System v.2.0.2	K102967	11/04/10
Smith & Nephew	Smith & Nephew SURESHOT™ Distal Targeting System v.2.1	K110240	4/14/11

A comparison of the subject device to the predicate devices is described in the following table.

Design Aspect Reviewed	SURESHOT™ Distal Targeting System v.3.0	SURESHOT™ Distal Targeting System v.2.1	PiGalileo Screw Targeting System V1.1	SURESHOT Distal Targeting System v.2.0	SURESHOT Distal Targeting System v.2.0.2
510(k) Number		**K110240**	K092497	K100107	K102967
Manufacturer	Smith & Nephew	Smith & Nephew	Smith & Nephew	Smith & Nephew	Smith & Nephew
Similar Indications for Use?	Y	Y	Y	Y	Y
Intended Use	Intraoperative image guided localization system				
Instrumentation	Used to assist surgeon in placing nail implants and for specific use with the distal targeting software				
Similar Sterilization?	Y	Y	Y	Y	Y
Similar Packaging?	Y	Y	Y	Y	Y
Similar Materials?	Y	Y	Y	Y	Y
Software Design	Provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. *Addition of drill depth measurement, Trauma Launcher updates, GUI updates, new instrument and Japan Nail application.*	Provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. *Addition of humeral nail application*	Provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data.		

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the SURESHOT™ Targeting System software modifications. Based on the similarities to the predicate components and a review of the validation testing performed, the device is substantially equivalent to above predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 4, 2013

Smith & Nephew, Inc.
% Mr. Bradley Heil
1450 Brooks Road
Memphis, Tennessee 38116

Re: K130748
Trade/Device Name: Sureshot Distal Targeting System V3.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 01, 2013
Received: July 03, 2013

Dear Mr. Heil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K130748

Device Name: SURESHOT Targeting System V3.0

Indications for Use:
The Smith & Nephew SURESHOT Targeting System is intended to be an intraoperative image guided localization system. It is a computer assisted orthopedic surgery tool to aid the surgeon with drill positioning for screws during intramedullary nail implantation. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. The Smith & Nephew SURESHOT Targeting System is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—Division Sign-Off	Joshua C. Nipper -S
Division of Surgical Devices	
510(k) Number: K130748	